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PATENT PROTECTION OVER TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES IN VIETNAM: THE CASE OF TRADITIONAL MEDICAL KNOWLEDGE

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Abstract

This paper aims to examine how the protection of traditional knowledge associated with genetic resources (ATK) in general and traditional medical knowledge (TMK) in particular under the patent regime has been legally governed and enforced in Vietnam and to what extent such legal framework responds to theoretical and practical challenges associated with TMK protection from the patent law perspective. To achieve these objectives, the paper investigates the related legal documents governing the subject matter with a main focus on Law on Intellectual Property Rights and Law on Biodiversity in Vietnam. Their workability in practice is assessed and thereby allows us to analyze the chances and the challenges faced by the system in TMK protection. This paper concludes that the vague and unenforceable provisions, lack of collaboration between the patent regime and the access and benefit sharing (ABS) framework under the Law on Biodiversity, and the lack of mechanisms for TMK holders to acquire and receive benefits from patent rights have contributed to the unworkability of the system. This paper also suggests that in light of experiences from TMK-rich nations, patent rules should move towards the trend that supportively enforces the ABS regime and a patent-adaptive or sui generis framework should be built to achieve more feasible ways of protection if the current patent model fails to protect the legal interests of TMK holders.

Keyword

traditional knowledge, traditional medical knowledge, patent

ベトナムの遺伝資源に関連する伝統的な知識に対する特許保護：伝統的な医療知識の事例

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要旨

本稿は，ベトナムにおいて一般的に遺伝資源（ATK）や具体的には伝統医療知識（TMK）に

関連する伝統的知識の保護が特許体制の下で，どのように合法的に統治され，実施されているか，特許法の観点から見たTMK保護に関連した理論的課題ならびに実践的課題がどの程度このような法的枠組みに影響を受けているかを調査することを目的としている。これらの目的のために，本稿は，知的財産権法と生物多様性法を中心に，その主題を支配する関連法律文書を調査し，その実用性を評価し，TMK保護におけるシステムが直面するチャンスと課題を明らかにする。本稿は，漠然とした法的強制力のない条項，生物多様性法の下での特許制度とABS（アクセスと便益の共有）枠組みの間の協力の欠如，TMK保有者が特許権を取得して利益を得る仕組みの欠如が，システムを阻害していると結論づける。本稿はまた，TMKの豊富な国々からの経験に照らして，ABS制度を実施するための特許規則を確立すべきであり，現在の特許モデルがMK保有者の法的利益を保護することに失敗しているのならば，より有効な保護方法を達成しなければならないことを指摘する。

キーワード
伝統的知識，伝統的医学知識，特許

A. INTRODUCTION

Nowadays, traditional medicine plays an important role in meeting the public health needs, contributing to national income and community's livelihood and playing as inputs in pharmaceutical researches for centuries, which led to discovery or inventions of a great deal of modern drugs. However, the incidents of unauthorized access and misappropriation of Traditional knowledge associated with Genetic resources (ATK), including Traditional Medical Knowledge (TMK), have not been an uncommon phenomenon worldwide, which is widely known as "bio-piracy". In these cases, bio-prospectors, most of whom are from developed countries, accessed ATK and utilized it as basis to develop their products, and obtained intellectual property rights (IPRs), particularly patent, over those products without sharing any benefits with the ATK holders.

The Convention of Biological Diversity (CBD) was concluded as a legal response to such unfair exploitation of ATK of developing countries by the developed world.[2] It requires member countries to establish mechanism for access and benefit sharing (ABS) within national legislations, under which access to ATK must be subject to prior informed consent (PIC) of ATK holders, and resulted benefits must be shared to the ATK holders (Art. 15 and Art. 8(j)). It also requires contracting parties to protect TK and customary practices related to uses of biological resources (Art. 10c).

In recognizing the great influence of IPRs regime, of which that of patent is specially emphasized, on the implementation the CBD's mentioned objectives, the CBD calls for the cooperation from IPRs related international laws in the manner that "should be supportive and do not run counter to the CBD's objectives…" (Art. 16.5).

In the patent perspective, the call for harmony between CBD framework and IPRs regime emanates from the fact that patent unwittingly facilitates bio-piracy due to its failure to define patentability in the manner to avoid misappropriation over ATK by

patent applicants, or more concretely, because ATK by its nature as an oral or unwritten knowledge is normally excluded from *prior art*. Additionally, conventional patent also fails to confer patent rights to indigenous people over their ATK since the existing regime does not accommodate distinctive features of ATK and raises difficulties for ATK to satisfy criteria of patentability (*novelty, non-obviousness and industrial applicability*). More debatedly, the existing international patent framework does not incorporate the requirements of prior informed consent or benefit-sharing related to inventions based on ATK.

In response to such call, in recent two decades, harmonization between CBD and IPRs regime has been controversially debated, negotiated by different international forums. In that vein, the World Intellectual Property Organization (WIPO) established the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) in 2000. Likewise, under the mandate of the 2001 Doha Declaration which requests the TRIPS Council to look at the relationship between the TRIPS Agreement and the CBD, the TRIPS Council began to examine the interface between the two regimes[3]. Although discussions are still ongoing, the two key demands for ATK protection (in respect of patent) have arisen in the policy debate: (a) Defensive protection, which aims to prevent third parties from obtaining patent over ATK illegitimately. This option could be done through several measures, such as *Documentation of ATK or Prior Art Databases, Inclusion of TK in International search, Disclosure of origin and evidence of compliance with ABS, Sharing of benefit resulting from Traditional knowledge (TK) based invention,* and (2) *Positive protection,* which aims at allowing ATK holders to take action to acquire legal rights over ATK or seek remedies against misuse of ATK. The objectives of this option can be achieved through existing patent laws, extended or adapted patent rights specifically focused on ATK (*sui generis* aspects of IP laws), and new, stand-alone *sui generis* systems for ATK.[4]

Since the CBD and related guidelines (Bonn Guideline in 2001 and Nagoya Protocol in 2010) leave discretion for contracting parties to decide the matters under their national legislations, and the debate over interface between the CBD and IPRs at global scale are still ongoing without any agreed upon approach thus far, domestic frameworks in each individual country have been of great importance to protect ATK in general and TMK in particular. Currently, in many developing countries, such as China, India, South Africa, Peru, Panama, etc.., national laws are the prime mechanism for achieving protection of TMK holders' legal interests.

Vietnam has estimated 12,000 species of high-value plants, of which 10,500 have been identified, and 36 per cent of which have medicinal properties. They account for approximately 11 per cent of the medicinal plants worldwide. TK associated with those medicinal plants by ethnic minority groups has contributed significantly to the available treatment options and plays roles as an integral part of the national health care system.[5]

Nevertheless, despite being a country rich in biodiversity, ATKs in Vietnam are largely fragmented, undocumented and have also been very susceptible to bio-piracy, which has left a vast majority of ATK holders in general and TMK holders in particular unprotected. Therefore, an effective mechanism for ABS and a strong patent framework as a supportive

measure is of great importance in response to the situation.

As a contracting party of the CBD and TRIPS, Vietnam assumes the responsibility to codify those international commitments into national laws. Therefore, a strong framework of patent incorporating requirements of ABS mechanism not only serves as a national response to such international commitments, but also actively contributes to justice for TMK holders.

From this fact, the paper aims at examining how the protection of ATK in general and TMK in particular under patent regime has been legally governed and enforced in Vietnam and to what extent such legal framework responses to theoretical and practical challenges associated with TMK protection in the patent law perspective. To achieve the objectives, after clarification of terminology, the paper figures out the need to protect TMK under patent regime in Vietnam by investigating some related case studies. After that, it provides the overview of the legal system in dealing with the matter, based on which the shortcomings or incompatibility of laws when applying in practice are analyzed. The last section gives conclusion on findings presented in the proceeding parts.

B. DISCUSSION

1. TERMINOLOGY

1.1. Traditional Knowledge (TK), Traditional Medical Knowledge (TMK) and Traditional Knowledge associated with Genetic Resources (ATK)

1.1.1. Traditional Knowledge (TK)

To date, there is no globally adopted definition of Traditional knowledge. This term has been used in various contexts where its connotation has been differently interpreted. In the absence of the single definition of TK and within the context of this paper, TK's definition from the WIPO and CBD's perspectives will best suffice to achieve the paper's objectives.

According to CBD's definition, TK *"refers to the knowledge, innovations and practices of indigenous and local communities around the world. Developed from experience gained over the centuries and adapted to the local culture and environment, traditional knowledge is transmitted orally from generation to generation. It tends to be collectively owned and takes the form of stories, songs, folklore, proverbs, cultural values, beliefs, rituals, community laws, local language, and agricultural practices, including the development of plant species and animal breeds. Sometimes it is referred to as an oral traditional for it is practiced, sung, danced, painted, carved, chanted and performed down through millennia. Traditional knowledge is mainly of a practical nature, particularly in such fields as agriculture, fisheries, health, horticulture, forestry and environmental management in general"*.[6] More specifically, in the milieu of IPRs, TK is defined by WIPO as those that *"refer to the content or substance of knowledge resulting intellectual activity in a traditional context, and includes the know-how, skills, innovations, practices, and learning that form part of traditional knowledge systems, and knowledge embodying traditional lifestyles of indigenous and local communities, or contained in codified knowledge systems passed between generations. It is not limited to any specific technical field, and may include agricultural, environmental and medicinal knowledge, and any traditional knowledge associated with genetic resources"*.[7]

To sum up briefly, TK, in broad sense, encompasses a wide range of subject areas from art to technical fields, including those pertaining to traditional use of plants for medical treatment (medicinal knowledge). Such knowledge is traditionally embedded in local context, orally passed down from generation to generation and owned collectively by indigenous and local communities. Being characterized as a specific type of intangible cultural heritage, TK, From an IP point of view, is referred to as "*knowledge resulting intellectual activity in a traditional context*", which represents as the starting point for the debate on the linkage between TK and IPRs' subject matters.

Under Vietnamese legislations, the term TK falls under the category of "intangible cultural heritages" provided in the Law on Cultural Heritage of 2001. "Intangible cultural heritages", as defined in the Law, are "*spiritual products of historical, cultural or scientific value, being saved in memory or in scripts, handed down orally and through professional teaching, performance and other forms of saving and handing down, including speech, scripts, literary, art or scientific works, oral philology, folk oratorio, life style, way of life, rites, traditional craft know-how, knowledge about traditional medicine and pharmacy, gastronomic culture, traditional costumes, and other folk knowledge*" (Art. 4 (1)). Accordingly, the TK definition in Vietnam also encompasses all common features of TK that are acknowledged globally.

1.1.2. Traditional Medical Knowledge (TMK) and Traditional Knowledge associated with genetic resources (ATK)

Traditional medical knowledge (TMK), as a specific type of TK, describes a group of health-care practices and products that has historically been used, maintained and developed by local and indigenous communities, which incorporates plant, animal and mineral-based medicines, spiritual therapies and manual techniques designed to treat illness or maintain well-being.[8] The term TMK has often been used interchangeably with the term "traditional medicine" whose definition was officially given by the World Health Organization (WHO) as: "*the sum total of the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health, as well as in the prevention, diagnosis, improvement or treatment of physical and mental illnesses*".[9] In the Vietnamese context, TMK, as literally interpreted from the text of intangible cultural heritage's definition (as above-mentioned), is regarded as a specific type of intangible cultural heritage although no specific definition of TMK is provided.

Since herbal medicine constitutes a substantial part of traditional medicine[10], TMK is often associated with genetic resources.[11] In this sense, TMK falls within the category of traditional knowledge associated with Genetic Resources (ATK) – a subject matter under the scope of the CBD. Therefore, the CBD, has frequently been referred to as an international hard-law instrument to achieve protection over TMK. In the national context, TMK is also protected under the auspice of the Vietnamese Law on Biodiversity, particularly in the framework governing ATK related matters.

1. 2. Patent

A patent is defined as a national grant of exclusive rights for a limited time to the holder

of a new, non-obvious and useful invention. Patent rights prevent others from selling, manufacturing, making, advertising, using or importing the protected invention or the idea over which an individual has a patent.[12]

To obtain a patent, the applicant must submit the formal application to the country where the patent protection is desired. Regarding substantial requirements, the invention must constitute patentable subject matter. For example, generally, discovery of nature is considered unpatentable. In addition, the invention must be new, non-obvious, and useful. However, because different countries define each of components of patentability by varying ways and degree, the same invention may be granted or denied as patent in different countries.

In relation to ATK generally and TMK particularly, within the international debate, patent and TK are not mutually supportive due to their contradictory characteristics, which may exacerbate the situation of bio-piracy. Therefore, the harmonizing approach that aims at rectifying the gap between the two regimes must be reached to bring equity to TK holders.

2. WHY PATENT PROTECTION FOR TMK IN THE VIETNAMESE CONTEXT?

We start the investigation by considering some real cases of alleged bio-piracy as below:

2.1. Case studies on misappropriation of TMK by foreigners

To date, two cases of IP acquisition over Vietnamese TMK by foreigners were observed. The first patent named Patent US 2003/0152651 A1 (granted on 31st July, 2002) was officially obtained by five co-owners: Xijun Yan, Naifeng Wu, ZhixinGuo, Zhengliang Ye, Yan Liu[13]. The patented invention concerns the method to treat angina pectoris by herbal composition. Actually, the patent's scientific nature originally came from Vietnamese traditional herbal formula named "*Gia Vi Ich Tam Khang*" that was collected and described in the book "*Thien Gia Dieu Phuong*" published by The Central Institute of Information and Library for Medical Sciences of Vietnam in 1989. However, no legal response has been raised against the US's patent so far by Vietnamese interested parties.

The second Patent named Patent US 7.514.092 B2 (granted on 7th April, 2009) was granted to two co-owners: Laurence Dryer, Dmitri Ptchelintseu[14]. The patented invention deals with skin treatments using any of three Asian plants, including Stephania rotunda (or *Binh Voi* in Vietnamese) - an unusually medical plant cultivated in Vietnam. In essence, the Vietnamese traditional use of *Binh Voi* for skin care was observed historically, but there's no published document recording such traditional knowledge.

Key issues: Inaccessibility of published prior art for foreign patent examiner may contribute to bio-piracy. Bio-piracy of unwritten TMK might also happen in foreign country like US where knowledge outside US territory is regarded as prior art only if being described in written publication.

2.2. Case study on the access and benefit sharing: *Nature's Way with Panaxvietnamensis*[15]

The case happened in the late 1990s in Vietnam. The involved parties include:

- Nature's Way: An US. Pharmaceutical company
- The Government of Vietnam (represented by the Ministry of Agriculture)
- People's Committee of Kon-tum Province

(Vietnam)

- Researchers from scientific institutes and universities
- Community of *Sudang* ethnic minority group in Kon-tum Province (Vietnam)

The Nature's Way concluded agreement with the Government of Vietnam and People's Committee of Kon-tum Province to access, cultivate, conduct scientific research and commercialize *Panaxvietnamenis*- an herbaceous medical plant in Ngoc Linh region, Kon-tum Province. It is used locally and historically by *Sedang* ethnic groupas a secret life – saving medicine for the treatment of a range of diseases and to enhance physical strength. The project was carried out with involvement of Nature's Way, central and local governments of Vietnam, researchers and local community of Sudang group, in which, related benefits would be shared as below:

- 70% of profit would go to Nature's way, 30% to the Government (Nature's Way would cover all cost of labor, materials and other expenses)
- Researchers would get benefit from equipment funding, training and support for graduation, research exchanges with US universities, sponsorships for scientific meetings, among other things
- Sudang community would be paid labor cost to cultivate *Panaxvietnamenis*

It should be noted that the agreement neglected the role of TMK of Sudang group, and tended to treat Panaxvietnamenis as physical material, therefore no compensation was paid for access and utilization of community's TMK associated with Panaxvietnamenis. The research process came up with a number of medical products, however, as of yet, no evidence has been shown about sharing of patent right of those products between Nature's Way and concerned parties, including Sudang community.

Key issue: The case reflects the unfairness of access and benefit sharing process where TMK holders held weak bargaining position. It also illustrates the vagueness of legal mechanism for sharing patent rights in case that the patent derives from TK of a community.

2.3. The case of TMK protection by IPRs mean other than patent: *Dao' Spa case*[16]

SaproNapro Company was established in 2006 with main products as bathing medicines of Dao ethnic minority. The company's shareholders include local communities who supply medicinal plants materials and provide TMK advice. The company's profits are paid annually to shareholders as dividend and a portion of profits are allocated to the communal development fund. The company was granted "Dao's Spa" Trademark for the bathing medicine on 17th November 2008.

However, products imitating Dao's Spa medicine appear in the market with a large quantity, in which producers clearly indicate the source of product as from Dao ethnic minority, but under the name of imitators' own businesses, not under the name of "Dao's Spa". Therefore, although economic loss of SaproNapro company was observed, no claim can be raised due to absence of IP law's violation.

Key issues: Despite not directly relevant to patent discussion, the case still shows that Trademark or other relevant IP instruments has only distinguishing function that could not prevent third parties from misuse of knowledge associated with products bearing trademark. Or in other words, Trademark does not function like patent to protect idea

or knowledge itself behind the product, which may facilitate bio-piracy as exemplified in the above case. It signifies the role of patent regime in solving this matter by considering patent rights for TMK holders.

The four above cases demonstrate the susceptibility of Vietnamese TMK to bio-piracy, either by legal or illegal way. They notice the urgent need to reduce the likelihood of future bio-piracy incidents and to restore justice by patent system. Therefore, a patent framework responsive to the need of TMK protection is of significance to deal with the situation.

3. LEGAL RESPONSE TO THE SITUATION

3.1. Protection of TMK in general

As discussed, in Vietnam, TMK falls within the category of intangible cultural heritage, which contributes to the legal base for TMK protection under the auspices of the Cultural Heritage Law. However, the Law takes the conservation-based approach with main focus on administrative measures rather than rights-based approach that enables economic exploitation of TK. With holistic language, the Law regards communities holding TK as TK stewards than as TK holders.

In contrast to the conservation – based approach of the Cultural Heritage Law, the Pharmaceutical Law of 2016 directs TMK protection with due regard to its property related aspects. More specifically, it affirms the State policies in "facilitating the discovery, clinical trial, registration of intellectual property rights of traditional medicine" (Art. 7 (7)) and "protecting confidentiality of information about concoction and clinical trial of traditional medicine". Nonetheless, the Law does not go further than declaration on the State policies over IPRs related aspects of TMK. Rather, it authorizes the Ministry of Science and Technology, in collaboration with the Ministry of Health, to develop policies on protection of IPRs over traditional medicine (Art. 10 (7,c)). As of yet, the matter has still been left unguided by the both Ministries in charge.

3.2. Protection of TMK by Patent regime

3.2.1. TMK and Prior art as defensive protection

One possible approach to protect TMK as widely discussed in global forums is to take measures aiming at preventing third parties from claiming and acquiring patent over TMK, so-called as the defensive protection. In Vietnam, this approach has also been taken by including TK into *prior art* to destroy the novelty of TK based invention.

Under the Vietnamese Law on Intellectual Property Rights (IP Law), prior art is defined as those that "has been publicly disclosed through use or by means of a written description or any other form, inside or outside the country, before the filing date or the priority date of the invention registration application" (Art. 60 (1) – IP Law). With such a wide definition of *prior art* that includes all knowledge existing under either written or oral forms, within or beyond the national jurisdiction, even known through use, the law automatically recognizes TK in general as prior art by virtue of its characteristics, such as being traditionally used by communities and transmitted orally from generation to generation, that suffice to qualify as prior art under the law. Accordingly, patent will not be given for an invention if it is merely a copy of idea from TK – even in the unwritten form or known by traditional use.

However, definition of prior art under the IP law only addresses the concern of potential bio-piracy that may happen within the Vietnamese

territory. In fact, bio-piracy is still likely to happen outside the country where prior art is narrowly defined or the TK related information is inaccessible for patent examiners. The case studies on misappropriation of TMK by foreigners illusstrates the situation. In the US, prior knowledge or use of an invention in a foreign country does not constitute prior art unless being described in a printed publication,[17] therefore undocumented TK would be legally pirated within that jurisdiction. In response to that situation, documentation of TK, as the measure of defensive protection that has been effectively applied in some TK rich countries like China and India, is implicitly referred in the Law on Biodiversity. The law states that: "The State protects *copyright of traditional knowledge* on genetic resources and encourages and supports organizations and individuals to register traditional knowledge copyrights on genetic resources." (Art. 64 (1)). Although the law does not directly use the term "documentation", it promotes fixation of TK to constitute prior art by guaranteeing the protection traditional knowledge via copyright tool. Such kind of written prior art is supposed to be a counter-measure against undesired use of TK happening in jurisdictions where undocumented TK does not constitute prior art, like the US. The law mandates the Ministry of Science and Technology[18] to provide guideline for the matter, however, no regulation has been put in place thus far to clarify such provisions. In the same token, the Decree guiding ABS issued by the Government, regarded as the first legal normative document incorporating Nagoya Protocol into national legal framework, does say nothing about protection of ATK through copyright or any other mean of IP.[19]

3.2.2. Disclosure of origin and evidence of compliance with ABS:

At global scale, this approach requires an amendment to the TRIPS to incorporate the obligation of disclosure of TK's origin and submission of relevant documents evidencing prior informed consent and benefit sharing agreement in the course of patent application.[20] Presumably, this would minimize incidents of misappropriation and supportively enforce ABS rules. Although this approach has not yet reached affirmative agreement among member of TRIPS[21], a number of countries have incorporated this requirement into domestic laws at varying levels.[22] Vietnam also adopted this approach by requiring patent applicants to "disclose the origin of accessed TK if the claimed patent is based on the TK in question"[23] and "in case where the inventor or applicant is unable to determine the origin, he/she should make a declaration about that and be responsible for the truthfulness of such declaration"[24]. It could be seen that Vietnam sets out very basic standard of disclosure that requires applicants to disclose the origin of the accessed TK from which the invention is derived, but does not oblige them to prove the consent of TK holders to use such TK or commitment to share patent related benefits. Also, failure of patent applicant to disclose the TK's origin does not result in revocation or delay of patent granting process.

3.2.3. Promoting sharing of benefits resulted from TK-based patent

Although the LoB does not provide mechanism for access and benefit sharing related to traditional knowledge, the law refers to the responsibility of those who access to copyright of traditional knowledge to share IP benefits

resulted from the invention based on traditional knowledge.[25] However, as of yet, there are neither official interpretation of "access to copyright of traditional knowledge" nor detailed guideline about IP benefits that should be shared between TK holders and patent owners. Besides, the law does not provide mechanism against non-compliance by ATK accessors.

3.2.4. The possibility of patenting TMK under the existing patent framework

Despite the fact that the TRIPS facilitates patent application without discrimination "as to the place of invention, the field of technology and whether products are imported or locally produced" (Paragraph 1, Art. 7 TRIPS), the common criteria of patentability unwittingly exclude TK from being patented. The incompatibility between patent and TK has been controversially debated in both academic and policy forums with a view to finding a feasible IP – adaptive framework or a sui generis framework to fit the distinctive features of traditional knowledge.

Within the Vietnamese context, there does not exist any specialized IP framework applying to TK. With regard to patent, the existing framework evidently reveals the conflict between TK and patent nature. For instance, according to Art. 59 of the IP law, scientific discovery falls outside the scope of patentable subject matters. Meanwhile, TMK has been largely considered as the discovery of nature since indigenous people practice traditional therapies by using raw herbs without any purification or alteration of natural substances. Moreover, concerning the criteria of "novelty" provided under Art. 60 (1) that requires the invention not to be: "publicly disclosed through use or by means of a written description or any other form, inside or outside the country, before the filing date or the priority date, as applicable, of the invention registration application", the use of TMK that has been observed largely in indigenous communities contributes to destroying "novelty" of TMK in practice. Similarly, as almost all traditional therapies base their remedies on using raw materials from nature, TMK finds hard to constitute an "inventive progress" set out as a patentability condition under Art. 61. In term of industrial applicability as provided in Art. 62, TMK also fails to satisfy the condition because of its impossibility "to realize mass manufacture or production of products or repeated application of the process that is the subject mater of the invention, and to achieve stable results".

Besides, there are still a number of matters raising obstacles in patenting TMK that remain unresolvable under the existing framework, such as the identification of inventors or limitation in protected time (20 years) due to the individual nature of patent that sharply contrasts with the collective or communal feature of TK. Those mentioned aspects of Vietnamese patent regime evidences the obvious incompatibility between the existing framework that adopts purely conventional approach and the TK that involves numerous distinctive natures.

4. PROSPECTIVE CHANCES AND LEGAL CHALLENGES IN PROTECTION OF TK BY PATENT

In the positive aspect, despite the vagueness of legal provisions concerning copyright of traditional knowledge associated with genetic resources, some projects have been carried out to document TMK and establish digital libraries on genetic resources and associated traditional knowledge.

However, as the matter of fact, the system still involves numerous obstacles challenging those communities who wish to seek patent protection over their TMK. Since the enactment of IP law, LoB and related guidelines, the legal system have not yet produced any promising results in practice. Among others, vagueness of legal provisions, weak collaboration between the fields of IP law and LoB, lack of mechanism for TMK holders to claim their patent rights have been contributed to such a situation, which are analyzed below.

4.1. Problem arising from "*copyright of ATK*"

As discussed, the implication of incorporating the term "*copyright of ATK*" into the LoB by the lawmakers could be explained in light of *defensive protection* measure, which aims at making ATK a part of *prior art*. However, since the enactment of the LoB, this legal provision has hardly taken effect in practice. Despite the ambiguity of the provision, there has been no guideline to clarify although the law explicitly designates the Ministry of Science and Technology to be responsible for this task.

The difficulty in enforcement of this provision has been construed by the fact that under the IP law there is no form of copyright work that fit the nature of ATK generally and TMK particularly[26], therefore it is still questionable by what way ATK is protected by copyright. Furthermore, Art. 60.2.c of LoB states the responsibility of those who get access to copyright of ATK to share benefits related to patented invention derived from access to *copyright of ATK*. However, in the purview of IP law, copyright in essence protects purely expression of idea or knowledge under a specific physical (or material) form, and does not afford protection of idea or knowledge itself. In this sense, copyright prevents third parties from copying or duplicating protected work containing knowledge, but does not exclude them from utilizing or exploiting such knowledge, even for commercial purposes, since such knowledge itself is not subject to copyright's protection. Therefore, if someone accesses ATK's copyright and subsequently get patent based on the ATK in question, it is unpersuasive to require him/her to share patent right with TK holders because TK holders is not granted monopoly over exploitation of such knowledge from the viewpoint of IP law. Accordingly, it has still been problematic for "*copyright of ATK*" to be implemented in practice.

Since the LoB came to effect, there has been no permit for accessing ATK officially granted, and as the result, there has been no sharing of patent right between patent owners and ATK holders based on officially mutually agreed contracts[27]. In fact, the cooperation between scientists, companies and indigenous communities still happen without official procedures given by the law[28]. However, it does not always end up with desired outcomes in favor of indigenous communities because of their weak bargaining power[29], or even in some cases with goodwill of scientists, indigenous people were still reluctant to share their secret TK due to "lack of legal guarantee for their interests"[30].

4.2. Weak collaboration between the two regimes

The linkage between the fields of IP, especially patent and ATK was once referred by the CBD through the call for IP, especially patent regime not to "run counter the CBD's objectives"[31]. The call has been commonly construed that IP generally and patent particularly should

not be developed in the way that facilitates bio-piracy or obstructs the access and benefit sharing related to ATK. Given the absence of strong international instrument in dealing with the matter, national IP law is of significance to achieve that goal.

However, in Vietnam, the linkage between IP law and LoB in regard of ATK protection has been touched upon through only one provision in the Guideline of the Ministry of Science and Technology as above-mentioned that merely requires the patent applicants to disclose the origin of the TK from which the claimed invention is derived. The evidence of agreement between patent applicants and TK holders about access and benefit sharing is not required to be shown as the condition of disclosure requirement. Apparently, "disclosure of origin" hardly becomes an instrument to enforce access and benefit sharing mechanism as the primary purpose discussed in CBD, TRIPS and WIPO forums. Not to mention the fact that the Guideline of the Ministry of Science and Technology was promulgated before the adoption of LoB[32], therefore, the provision of "disclosure of origin" is not presumed to serve the purpose of enforcement of LoB. Furthermore, in its amendment in the Circular 05/2013/TT-BKHCN after enactment of LoB, the Guideline still fails to rectify this gap.

The patent regime also fails to deal with sharing of patent right between ATK holder and patent owner in the case that the patented invention is derived from the ATK in question. It is still unclear whether or under what conditions ATK holders are recognized as "co-owners" or "co-inventors".

In the draft the Decree on management of access and benefit－sharing of genetic resources and associated traditional knowledge (finally promulgated as the Decree 59/2017/ND-CP), there is one provision stating that: "the grant of patent to the invention based on ATK needs consent from ATK holders" and "communities holding ATK must be shared IP right associated with such invention in any way"[33]. Nonetheless, the National Office of Intellectual Property of Vietnam (under the Ministry of Science and Technology) – the State organ who assumes the primary responsibility in taking initiative in IP legal reform commented "the drafted provision sharply contradicts to the current patent framework that does not require patent applicant to show any evidence of consent of ATK holders or agreement of benefit-sharing"[34]. It also noted: "the unidentification of inventors or owners of ATK, the transgenerational nature of ATK that contrasts with the limitation in protected time of patent and so on make granting or sharing patent right with ATK holders impossible"[35]. Therefore, This provision was finally removed from the official text of the Decree 59/2017/ND-CP. It demonstrates not only the big gap between the two regimes, but also the reluctance and weak collaboration to make the two regimes mutually supportive.

4.3. Lack of mechanism for TMK holders to claim their patent right

While placing strong emphasis on *defensive protection*, the legal system seems to neglect the *positive protection* that aims at allowing TMK holders to acquire IP rights over TMK or seek remedies against misuse of TMK. Or in other words, the system does not directly address the exclusive or proprietary aspect of TMK. Although defensive protection has been largely recognized by commentators as the "more achievable than positive protection"[36], experiences from some countries show that it is useful

merely for the sake of defensive claims against misappropriation by outsiders, but helpless for indigenous communities to pursue commercial benefits based on such TK. By publishing or documenting, TK will be publicly available and no longer under control of TK holders, which facilitates unauthorized use by third parties without any sharing of benefit. Even India – with Traditional Knowledge Digital Library that has successfully prevented third parties from acquiring patent over TK – has still not shown any success in commercial exploitation over TKDL.[37] In fact, misappropriation is not sole concern of TK holders. In Hoodica case[38], for instance, TK holders' concern did not center on whether the patent should be granted but whether fair share of benefit would be given to TK holders. In this regard, defensive protection fails to respond to the latter concern raised by the community.

In Vietnamese context, the *positive protection* does not work since the system still maintains a strict patent model applying to all subject matter without due regard to the distinctive features of those as TK. In fact, patents related to TMK have still been granted as in the table below:

However, those patents were granted to only individuals who made inventions developed from TMK. Communities are not subject to such kind of grant. Considering the patent – adaptive or sui generis framework for TK, thus far, there is no legal initiative from State organs in charge to put it in law-making agenda.[39]

C. THE TREND FORWARD AND CONCLUSION

The above analysis reflects fragmentation and numerous obstacles, shortcomings, contradictions among legal documents governing IP protection over TMK. As the matter of fact, this unsolved legal problem still raises concerns of policy makers, illustrated by the mandate set out in the Decision 1250/QD-TTg of the Prime Minister on National Strategy on Biodiversity, which requests to "find protective measures over ATK", and in the Decision 1141/ QD-TTg of the Prime Minister on strengthening capacity in managing ABS, which calls for "studying and acquiring international experiences and practices on access to GRs and ATK, involvement of stakeholders and mechanism for management, sharing of benefit

Table 1: The number of applicants of patent related to TMKin Vietnam from 1998 to 2012

The total of applicants applying for patents in Vietnam	*Vietnamese Applicants*	*Chinese Applicants*	*Indian Applicants*	*US's Applicants*
69	27, of which 12 were granted patents	8, of which 4 were granted patents	3, of which 1 were granted patents	4, of which 2 were granted patents

Source: http://iplib.niop.govn/WebUI/WSearchPAT.php

resulting from ulilization of GRs and ATK" and "reviewing, establishing and reforming policies, legal documents guiding management of ABS". In the long-run, the legal reform is expected to progress towards a trend feasible for protection of ATK generally and TMK particularly in practice, in which "international experiences and practices" would be indispensable to achieve that goal. In that process, in light of experiences from TMK-rich countries, the reform of patent law should go hand in hand to enforce ABS rules and the strictly patent-based model for protection of TMK should be shifted toward an approach that aims to take into account all distinctive natures of TMK to achieve more feasible ways of protection.

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26 Art. 14 (1) of IP law provides the types of works covered by copyright, including: *Literary and scientific works, textbooks, teaching courses and other works expressed in written languages or other characters; Lectures, addresses and other sermons; Press works; Musical works; Dramatic works; Cinematographic works and works created by a process analogous to cinematography; Plastic-art works and works of applied art; Photographic works; Architectural works; Sketches, plans, maps and drawings related to topography or scientific works; Folklore and folk art works of folk culture; Computer programs and compilations of data.* Hence, ATK does not fall within any provided category to qualify as copyrighted work. About this aspect, see more at Tran Van Hai, *Commercial exploitation of Traditional Knowledge– from the perspective of Intellectual Property Rights (Khai thac thuong mai doi voi tri thuc truyen thong nhin tu goc do quyen so huu tri tue)*, Journal of Science and Technology *(Tap chi hoat dong khoa hoc)*, No. 3, 2012, pp. 54－59

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